[6450-01-P]

**DEPARTMENT OF ENERGY** 

**10 CFR Part 835** 

[Docket No. AU-RM-16-ORP]

RIN 1992-AA51

**Occupational Radiation Protection** 

**AGENCY:** Office of Environment, Health, Safety and Security, U.S. Department of Energy.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The U.S. Department of Energy (DOE) proposes to amend the values listed in two appendices to its current occupational radiation protection regulations. The proposed amendment to appendix C would correct the derived air concentration value for any single radionuclide not listed in the appendix C table with a decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than two hours, adjusted for an 8-hr work day. The proposed amendments to appendix E would correct the activity information of two radionuclides, Rh-102 and Rh-102m.

**DATES:** The comment period for this proposed rule will end on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by docket number AU-RM-16-ORP, and/or Regulation Identification Number (RIN) 1992-AA51 in one of four ways (please select only one of the ways listed):

1. Federal e-Rulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Follow the instructions for submitting comments.

- 2. *E-mail*: James.dillard@hq.doe.gov. Include docket number AU-RM-16-ORP and/or RIN 1992-AA51 in the subject line of the email. Please include the full body of your comments in the text of the message or as an attachment. If you have additional information such as studies or journal articles and cannot attach them to your electronic submission, please send them on a CD or USB flash drive to the address listed in paragraph 4. The additional material must clearly identify your electronic comments by name, date, subject, and docket number AU-RM-16-ORP.
- 3. *Mail*: Address written comments to James Dillard, U.S. Department of Energy, Office of Environment, Health, Safety and Security, Mailstop AU-11, Docket Number AU-RM-16-ORP, 1000 Independence Ave., S.W., Washington, D.C. 20585 (due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt). If possible, please submit all items on a CD or USB flash drive, in which case it is not necessary to include printed copies.
- 4. *Hand Delivery/Courier*: James Dillard, U.S. Department of Energy, Office of Environment, Health, Safety and Security, 19901 Germantown Road, Germantown, MD 20874. Telephone 301-903-1165. If possible, please submit all items on a CD or USB flash drive, in which case it is not necessary to include printed copies.

For detailed instructions on submitting comments and additional information on the rulemaking process, see Section IV of this document (Public Participation).

**Docket**: The docket, which includes <u>Federal Register</u> notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at <a href="http://www.regulations.gov">http://www.regulations.gov</a>. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available. A link to the docket web page

can be found at: http://www.ecfr.gov/cgi-bin/text-

idx?tpl=/ecfrbrowse/Title10/10cfr835\_main\_02.tpl. The www.regulations.gov web page contains instructions on how to access all documents, including public comments, in the docket. See Section IV of this document (Public Participation) for further information on how to submit comments through http://www.regulations.gov.

**FOR FURTHER INFORMATION CONTACT:** James Dillard, U.S. Department of Energy, Office of Environment, Health, Safety and Security, Mailstop AU-11, 1000 Independence Ave., S.W., Washington, D.C. 20585. Telephone: 301-903-1165. E-mail: james.dillard@hq.doe.gov.

#### SUPPLEMENTARY INFORMATION:

- I. Background
- II. Discussion of Proposed Amendments
  - A. Appendix C—Derived Air Concentration (DAC) for Workers from External Exposure During Immersion in a Cloud of Airborne Radioactive Material
  - B. Appendix E—Values for Establishing Sealed Radioactive Source Accountability and Radioactive Material Posting and Labeling Requirements
- III. Procedural Requirements
  - A. Review under Executive Orders 12866 and 13563
  - B. Review under the Regulatory Flexibility Act
  - C. Review under the Paperwork Reduction Act
  - D. Review under the National Environmental Policy Act
  - E. Review under Executive Order 12988
  - F. Review under Executive Order 13132
  - G. Review under Executive Order 13175
  - H. Review under the Unfunded Mandates Reform Act of 1995
  - I. Review under Executive Order 13211
  - J. Review under the Treasury and General Government Appropriations Act, 1999
  - K. Review under the Treasury and General Government Appropriations Act, 2001
- IV. Public Participation
- V. Approval of the Office of the Secretary.

## I. Background

The requirements in title 10, Code of Federal Regulations, part 835 (10 CFR part 835), *Occupational Radiation Protection*, are designed to protect the health and safety of individuals

from ionizing radiation resulting from the conduct of U.S. Department of Energy (DOE) activities.. One situation that DOE's regulations address is the exposure of workers to radioactive material dispersed in the air. Based on calculations involving doses to the organs of the body, levels of contamination in the air that will not cause the dose limits for workers to be exceeded are established for specified radionuclides. These values are provided in appendix C of part 835. On April 13, 2011, the Department published updated Derived Air Concentration (DAC) values in appendix C for determining radiation dose from inhaled radioactive material (76 FR 20489). The updated dose conversion factors were based on an 8 hour work day exposure time instead of the previously assumed 24 hour calendar day exposure, which is consistent with other occupational scenarios, such as those used in developing appendix A DACs. In that update, the DAC values for radionuclides not listed in the appendix C table with a decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than two hours were inadvertently not revised for the 8 hour work day exposure time. The proposed amendment to appendix C would provide the correct DAC values for this group of radioactive materials.

Title 10 CFR part 835 appendix E values were developed to ensure the proper accountability of sealed radioactive sources, as well as radioactive material posting and labeling requirements (63 FR 59662, November 4, 1998). DOE most recently amended the values of appendix E to part 835 on June 8, 2007 (72 FR 31904), using the International Commission on Radiological Protection (ICRP) Publication 60 methodology (ref. 1) and the same exposure scenarios discussed in a 1998 amendment to 10 CFR part 835 (63 FR 59662, November 4, 1998). The values were based on the more limiting of the quantity of radioactive material which results in either an external or internal whole body dose, from either inhalation or ingestion, of

100 millirems. However, the final rule incorrectly listed values for two radionuclides. This proposed amendment to appendix E would provide the correct activity values for these two radionuclides (Rh-102 and Rh-102m), calculated from internal exposure scenario derived from ICRP Publication 119 (ref. 2).

## **II. Discussion of Proposed Amendments**

A. Appendix C—Derived Air Concentration (DAC) for Workers from External Exposure During Immersion in a Cloud of Airborne Radioactive Material. The proposed amendment would provide a correction to the derived air concentration value for any single radionuclide not listed in the Appendix C table with a decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than two hours to 1E-06 µCi/mL (7E+04 Bq/m³).

B. Appendix E—Values for Establishing Sealed Radioactive Source Accountability and Radioactive Material Posting and Labeling Requirements. The proposed amendment would correct the activity for Rh-102 to 6.4E+05 μCi and the activity from Rh-102m to 3.0E+05 μCi.

## **III. Procedural Requirements**

#### A. Review under Executive Order 12866

This regulatory action has been determined not to be "not significant" under Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB).

## B. Review under the Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires that a Federal agency prepare an initial regulatory flexibility analysis for any regulation for which a general notice of proposed rulemaking is required, unless the agency certifies that the rule, if promulgated, will

not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)).

This proposed rule would amend DOE requirements for nuclear safety and occupational radiation protection at DOE sites. The requirements of part 835 are primarily implemented by contractors who conduct work at DOE facilities. DOE considered whether these contractors are "small businesses" as the term is defined in the Regulatory Flexibility Act (5 U.S.C. 601(3)). The Regulatory Flexibility Act's definition incorporates the definition of small business concerns in the Small Business Act, which the Small Business Administration (SBA) has developed through size standards in 13 CFR part 121. The DOE contractors subject to this rule exceed the SBA's size standards for small businesses. In addition, DOE expects that any potential economic impact of this rule would be negligible because DOE activities are conducted by contractors who are reimbursed through their contracts with DOE for the costs of complying with DOE nuclear safety and radiation protection requirements, including the costs of complying with the proposed rule. For these reasons, DOE certifies that this proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities, and therefore, no regulatory flexibility analysis has been prepared. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel of Advocacy of the SBA pursuant to 5 U.S.C. 605(b).

## C. Review under the Paperwork Reduction Act

This proposed rule does not impose a collection of information requirement subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

## D. Review under the National Environmental Policy Act

DOE has concluded that promulgation of this rule falls into a class of actions that would not individually or cumulatively have a significant impact on the human environment, as determined by DOE's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Specifically, this rule amends existing regulations without changing the potential environmental effect of the regulations being amended, and, therefore, is covered under the Categorical Exclusion in paragraph A5 of appendix A to subpart D, 10 CFR part 1021. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

## E. Review under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform" (61 FR 4729, February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. Section 3(b)(2) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any, to be given to the regulation; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any, to be given to the regulation; (5) defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether

they are met or it is unreasonable to meet one or more of the standards. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

#### F. Review under Executive Order 13132

Executive Order 13132, "Federalism" (64 FR 43255, August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this proposed rule and has determined that it would not preempt State law and would not have a substantial direct effect on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

#### G. Review under Executive Order 13175

Under Executive Order 13175 (65 FR 67249, November 6, 2000) on "Consultation and Coordination with Indian Tribal Governments," DOE may not issue a discretionary rule that has "tribal" implications and imposes substantial direct compliance costs on Indian tribal governments. DOE has determined that the proposed rule would not have such effects and concluded that Executive Order 13175 does not apply to this proposed rule.

## H. Review under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), 2 U.S.C 1531 *et seq.*, requires each Federal agency to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency regulation that may result in the expenditure by states,

tribal, or local governments, on the aggregate, or by the private sector, of \$100 million in any one year. The Act also requires a Federal agency to develop an effective process to permit timely input by elected officials of state, tribal, or local governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity to provide timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. DOE has determined that the proposed rule published does not contain any Federal mandates affecting small governments, so these requirements do not apply.

## I. Review under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to the OMB a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy and is therefore not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

# J. Review under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well-being. The proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

## K. Review under the Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB.

OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

## IV. Public Participation

Submission of comments

DOE will accept comments, data and information regarding this proposed rule before or after the public hearings, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested individuals are invited to participate in this proceeding by submitting data, views, or arguments with respect to this proposed rule using any of the methods described in the **ADDRESSES** section at the beginning of this proposed rule. To help the Department review the submitted comments, commenters are requested to reference the paragraph(s), e.g., §835.3(a), to which they refer where possible.

1. Submitting comments via www.regulations.gov. The www.regulations.gov web page will require you to provide your name and contact information. Your contact information will be viewable to DOE's Office of Environment, Health, Safety and Security staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment. However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to www.regulations.gov information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through www.regulations.gov cannot be claimed as CBI. Comments received through the web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section below.

DOE processes submissions made through www.regulations.gov before posting them.

Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable

for up to several weeks. Please keep the comment tracking number that www.regulations.gov provides after you have successfully uploaded your comment.

2. Submitting comments via email, mail or hand delivery/courier. Comments and documents submitted via email, mail, or hand delivery/courier, also will be posted to www.regulations.gov. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery/courier, please provide all items on a CD or USB flash drive, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

3. Confidential Business Information. Pursuant to the provisions of 10 CFR 1004.11, anyone submitting information or data he or she believes to be confidential and exempt by law from public disclosure should submit via email, or postal mail two well-marked copies: one copy of the document marked "CONFIDENTIAL BUSINESS INFORMATION" including all the information believed to be confidential, and one copy of the document marked "NO

CONFIDENTIAL BUSINESS INFORMATION" with the information believed to be confidential deleted. Submit these documents via email or CD, if feasible. DOE will make its own determination as to the confidentiality of the information and treat it accordingly. Factors of interest to DOE when evaluating requests to treat submitted information as confidential include:

(1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

4. Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

## **Appendix A—References**

- 1. International Commission on Radiological Protection (ICRP), 1994. *Dose Coefficients for Intakes of Radionuclides by Workers*. ICRP Publication 68. Ann. ICRP 24 (4).
- 2. ICRP, 2012. Corrigenda to ICRP *Publication* 119: Compendium of Dose Coefficients based on ICRP *Publication* 60. Ann. ICRP 41(suppl.).

# V. Approval of the Office of the Secretary.

The Secretary of Energy has approved publication of this proposed rule.

# **List of Subjects in 10 CFR Part 835**

Federal buildings and facilities, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Nuclear safety, Occupational safety and health, Radiation protection, and Reporting and recordkeeping requirements.

Issued in Washington, D.C., on October 31, 2016.

# Matthew B. Moury,

Associate Under Secretary for Environment, Health, Safety and Security.

For the reasons set forth in the preamble, the Department of Energy proposes to amend part

835 of chapter III of title 10 of the Code of Federal Regulations as set forth below:

PART 835—OCCUPATIONAL RADIATION PROTECTION

1. The authority citation for part 835 continues to read as follows:

**Authority:** 42 U.S.C. 2201, 7191, 50 U.S.C. 2410.

**Appendix C to Part 835—[Amended]** 

2. At the end of the table, in appendix C, the last sentence is amended by removing "6 E-06

 $\mu$ Ci/mL (2 E+04 Bq/m<sup>3</sup>)" and adding in its place "1 E-06  $\mu$ Ci/mL (7 E+04 Bq/m<sup>3</sup>)".

**Appendix E to Part 835—[Amended]** 

3. Appendix E is amended by removing the activity value in the second column for:

a. Rh-102, value of "3.0E+05" and adding in its place "6.4E+05"; and

b. Rh-102m, value of "6.4E+05" and adding in its place "3.0E+05".

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